DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

3172 '02 FEB 14 P1:18

FEB 13 2002

Arnall Golden Gregory, LLP
Attention: Alan Minsk
1201 West Peachtree Street, Suite 2800
Atlanta GA 30309-3450

Docket No. 01P-0585/CP1

Dear Sir:

This is in reference to your citizen petition, dated December 26, 2001, requesting the Food and Drug Administration to require the applicant of an abbreviated new drug application (ANDA) for immediate-release tablets containing mixed amphetamine salts to conduct certain bioequivalence testing prior to approval of the ANDA.

The agency expects to complete its review of the petition by the end of this month. In the meantime, you should know that in addition to in vitro data, the agency does require, as you request in your petition, that an applicant submit in vivo evidence of bioequivalence against the reference listed drug product, Adderall® Tablets, prior to approval of an ANDA. This and the other issues raised in the petition will be addressed in greater detail in the agency's forthcoming response.

Sincerely yours,

Gary Buehler
Director
Office of Generic Drugs
Center for Drug Evaluation and Research

cc: Dockets Management Branch (HFA-305)
(Docket No. 01P-0585/CP1)

01P-0585

LET2